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EXAMINER	
WILSON, J	
ART UNIT	**PAPER NUMBER**
1803	3

18M2/0118

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DATE MAILED: 01/25/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1 - 8 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 - 8 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claims 4-8 are objected to under 37 C.F.R. § 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See M.P.E.P. § 608.01(n). Accordingly, claims 4-8 have not been further treated on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention and failing to adequately teach how to make and or use the invention (i.e. failing to provide an enabling disclosure).

A disclosure in an application, to be complete, must contain such description and details as to enable any person skilled in the art or science to which it pertains to make and use the invention as of its filing date, In re Glass, 181 USPQ 31; 492 F2.d 1228

(CCPA 1974). While the prior art setting may be mentioned in general terms, the essential novelty, the essence of the invention, must be described in such details, including proportions and techniques where necessary, as to enable those persons skilled in the art to make and utilize the invention.

Markush claims should be provided with adequate support in the disclosure for the scope of the members set forth therein. Markush claims are subject to rejection based upon the lack of supporting disclosure when the "working examples" fail to include written description(s) which teach how to make and use Markush members embraced thereby in full, clear and exact terms, see In re Fouche (CCPA 1971) 439 F2d 1237, 169 USPQ 429. At present, it is noted that the instant specification fails to establish that the members of the Markush groups for the 3'-protecting groups, embraced by the claims may be used interchangeably, as is instantly asserted. The specification denotes the use of a plethora of protecting groups in the instantly claimed compounds. It is noted however, that applicant has not used an adequate representation of members to support the plethora of moieties asserted. There is not seen adequate support in the instant specification for making and using nucleoside compounds which are protected in the 3'-position with members of the Markush group which include carbonitriles, carbonates, carbamates, borates, nitrates, sugars, phosphoramidites, phenylsulfenates, sulfates or sulfones. The terms esters, ethers and phosphates are seen to be unduly broad. The

examples in the specification appear to be limited to esters such as carboxylic acid esters, isovaleroyl; certain ethers, such as silyl and methoxymethyl ethers, and phosphate esters. It is not the mere fact of breadth of compound claims that is considered under 35 USC 112, but the relationship of this factor to the entire picture presented in the instant case with particular attention to the supporting disclosure in eyes of persons of ordinary skill in this art.

Claims 1-3 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-3 are rejected under 35 U.S.C. § 103 as being unpatentable over each of the Andrus et al. patent, 4,816,571, the

Cruickshank patent 5,091,519 and the Bennett et al. reference, Biochemistry, Vol. 12, No. 20, pages 3956-3960, (1973), and the Kaufmann et al. reference, Eur. J. Biochem. Vol 24, No. 1, pages 4-11, (1971).

Claims 1-3 are drawn to nucleoside 5'-phosphate compounds which are blocked in the 3'-position with removable blocking groups.

The Andrus et al. patent discloses capping of the 3'-hydroxy position of a nucleotide. Though the nucleotide may be connected in series to other nucleotides, the attachment of a removable blocking group at the 3'-position is still seen to render the instant claims drawn to removable blocking groups at the 3'-hydroxy position obvious. The removable protecting groups disclosed in the Andrus et al. patent include phosphate blocking groups which are esters. Specifically, see column 2, lines 67-68, wherein removable phosphite monoesters are disclosed.

The Cruickshank patent teaches the attachment of removable blocking groups. In column 14, the 3'-position may be acetyl or phosphoramidite moieties. Each of these moieties renders the instantly claimed compounds obvious, specifically when the variable "X" in the 5'-position is a triphosphate. It is noted that the Cruickshank reference teaches the interchangeability of the mono-, di- and triphosphate moieties.

The Bennett et al. reference cited supra discloses 3'-methoxyethyl protecting groups for the 3'-position of a 5'-

phosphate nucleoside compound, see page 356, column 2 and formula I on page 3957, in FIGURE 1.

The Kaufmann et al. reference discloses 3'-O-isovaleryl nucleoside diphosphates, see page 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to obtain a 3'-protected 5'-nucleoside phosphate, wherein said 3'-protecting group is removable. Each of the following protecting groups, which are esters, a phosphates, and a methoxyethyl or an iosvaleryl protecting group renders the instantly claimed invention obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James O. Wilson whose telephone number is (703) 308-4624 or to his immediate supervisor, Douglas W. Robinson, SPE 1803, whose telephone number is (703) 308-2897.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

JAMES O. WILSON
PATENT EXAMINER
GROUP 1800